

REMARKS

I. Status of the Application

Claims 1-27 are presently pending in the application. Claims 13-27 have been cancelled without prejudice to the filing of any appropriate continuation applications as being drawn to non-elected subject matter. Claims 1-12 stand rejected under §112, second paragraph, as being indefinite. Claims 1-2 and 5-12 stand rejected under §102(b) as anticipated by Layrolle et al., U.S. Patent No. 6,207,218.

Applicants have amended the claims to more clearly define and distinctly characterize Applicants' novel invention. The amendments to the claims can be found in the specification and the claims as originally filed. Specifically, support for the amendment to claim 1 to recite "placing the medical device in the reactor" can be found in the specification at least at page 3, line 28 to page 4, line 1, where Applicants teach putting a medical device in a reactor. Support for the amendment to claim 1 to recite "contacting the medical device in the reactor with a solution including inorganic ions; depositing inorganic ions on the medical device; passing the solution including non-deposited inorganic ions through the at least one partition" can be found in the specification at least at: page 3, line 28 to page 4, line 3, where Applicants teach bringing a medical device into contact with a coating solution in a reactor so that a coating solution in the reactor can pass through the reactor via one or more partitions; page 7, lines 19-21, where Applicants teach inorganic ions forming a coating; page 4, line 26 to page 5, line 2, where Applicants teach a partition to separate inorganic ions and one or more bioactive agents from each other; and page 11, lines 3-10, where Applicants teach a coating solution having various concentrations of ions. Support for the amendment to claim 1 to recite "contacting the medical device in the reactor with a bioactive agent; and retaining the bioactive agent in the reactor" can

be found in the specification at least at page 3, line 28 to page 4, line 3, where Applicants teach bringing a medical device in contact with a coating solution and retaining the bioactive agent inside the reactor via one or more partitions. Claims 2, 3, 7 and 11 were amended to address formal matters. The amendments presented herein add no new matter.

Applicants respectfully request entry and consideration of the foregoing remarks, which are intended to place this case in condition for allowance.

II. Claims 1-12 Are Definite

At page 2, section 3 of the instant Office Action, claims 1-12 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants respectfully traverse this rejection.

The Examiner is of the opinion that claim 1 is unclear as to what is being retained by the reactor and what is passing through the reactor. The Examiner is also of the opinion that the claim does not make clear if the inorganic ions and bioactive agent are meant to be different materials. The Examiner helpfully suggests that the elements of the preamble be incorporated into the body of the claim and that the claim be clarified to recite a medical device substrate and a coating step, along with clarification of the materials which coat the substrate and which materials pass through versus remain within the reactor.

Without acquiescing to the rejection, Applicants respectfully submit that claim 1 has been amended to clarify that which was inherent in the claim. Specifically, claim 1 was amended to recite a partition that retains a bioactive agent in the reactor, depositing inorganic ions and the

bioactive agent on the medical device, passing the solution including non-deposited inorganic ions through the partition, and retaining the bioactive agent in the reactor.

The Examiner has requested that claim 7 be amended to spell-out the terms “HEPES” and “Tris.” In response, Applicants have amended claim 7 to replace these terms with “N-2-hydroxyethylpiperazine-N'-4-ethane sulfonic acid” and “tris(hydroxymethyl)aminomethane,” respectively.

Accordingly, Applicants submit that the claims are definite and respectfully request that the rejection of claims 1-12 under 35 U.S.C. §112, second paragraph be reconsidered and withdrawn.

III. Claims 1, 2 and 5-12 Are Novel over Layrolle et al., U.S. Patent No. 6,207,218

At page 3, section 5 of the instant Office Action, claims 1, 2 and 5-12 stand rejected under 35 U.S.C. §102(b) as being anticipated by Layrolle et al., U.S. Patent No. 6,207,218. The Examiner asserts that Layrolle et al. teaches depositing inorganic ions from a stream of bubbled carbon dioxide, and that the carbon dioxide/water solution acts as Applicants’ “coating solution” because it acts to deposit or coat the inorganic ions by affecting the pH. The Examiner states that the carbon dioxide/water solution is passed through the reactor as it bubbles out, and that the inorganic ions act as the bioactive agent, which are retained by a partition of the reactor. The Examiner states that Layrolle et al. teaches the use of plural organic layers, and that each layer may be applied using the bubbled carbon dioxide, providing the acidic solution claimed by Applicants, which would re-dissolve the inorganic salts and obtain a coating of the inorganic bioactive agent. The Examiner further asserts that Layrolle et al. teaches the concentrations of claims 7 and 12, teaches coating medical substrates of the materials of claim 8, and teaches the

use of other bioactive agents other than organic ions, such as peptides, growth factors, and bone morphogenic proteins, all of which would be “retained” in the reactor as the carbon dioxide is bubbled through. Applicants respectfully traverse this rejection.

The amended claims are directed to a method for coating a medical device comprising providing a reactor having at least one partition that retains a bioactive agent in the reactor; placing the medical device in the reactor; contacting the medical device in the reactor with a solution including inorganic ions; depositing inorganic ions on the medical device; passing the solution including non-deposited inorganic ions through the at least one partition; contacting the medical device in the reactor with a bioactive agent; and retaining the bioactive agent in the reactor such that the bioactive agent is deposited on the device.

The claimed method has many advantages over methods known in the art. Applicants’ method enables the production of medical implants having a specific amount of bioactive agents thereon (page 3, lines 13-26). In addition, because the claimed method uses a partition to prevent a bioactive agent from passing through the reactor while allowing a coating solution to be passed through, only small amounts of bioactive agent are needed to achieve a suitable amount of bioactive agent on the medical implant (page 4, lines 1-5). Furthermore, the claimed method can produce medical implants having much higher concentrations of bioactive agent than can be achieved using methods known in the art. For instance, using the claimed method, Applicants were able to incorporate at least ten times as much antibiotic than could be achieved using conventional plasma spray coating methods (Example 4, figures 7 and 8). Incorporating a sufficient amount of bioactive agent can increase success of the implant by positively affecting biological activities such as an immune response, tissue growth, cell growth, cell differentiation,

and cell proliferation, thus promoting a therapeutic or prophylactic affect in the individual receiving the implant (Example 4, page 4, lines 18-21).

Layrolle et al. fails to teach or suggest each and every element of the claimed invention. Layrolle et al. is directed to a method for coating a medical implant by soaking the implant in a calcifying solution and bubbling carbon dioxide gas passed into the solution (column 2, lines 3-14; column 8, lines 19-23). Escape of carbon dioxide gas from the solution causes a layer of carbonated calcium phosphate to form on the implant (column 8, lines 19-23). Layrolle et al. teaches that their carbonated calcium phosphate coatings may include bioactive agents, and that bioactive agents may be added to the calcifying solutions to achieve this result (column 9, lines 53-65). Nowhere, however, does Layrolle et al. teach or suggest a partition that selectively allows certain compounds to pass through while retaining others, let alone a reactor having a partition that retains a bioactive agent but allows a solution including inorganic ions to pass through, or the use of such a partition in the claimed method.

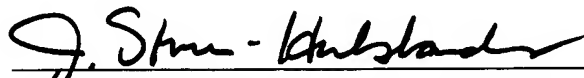
As Layrolle et al. fails to teach or suggest each and every element of the claimed method, this reference fails to anticipate Applicants' claimed invention. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of claims 1, 2, and 5-12 under §102(b) over Layrolle et al.

IV. Conclusion

Having addressed all outstanding issues, Applicants respectfully request reconsideration and allowance of all pending claims. To the extent the Examiner believes that it would facilitate allowance of the case, the Examiner is requested to telephone the undersigned at the number below.

Respectfully submitted,

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